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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,989	11/16/2001	Per Franklin Nielsen	6249.200-US	3031
7590	06/14/2004		EXAMINER	
Reza Green, Esq. Novo Nordisk of North America, Inc. Suite 6400 405 Lexington Avenue New York, NY 10174-6401			CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 06/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,989	NIELSEN ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

1. An analogue of GRP having Seq. ID No.2, wherein Xaa at position 1 is:
 - a) Val
 - b) Pyroglutamic acid
2. An analogue of GRP having Seq. ID No.2, wherein Xaa at position 2 is:
 - c) Pro
 - d) Gly
 - e) Val
 - f) Ile
 - g) Thr
3. An analogue of GRP having Seq. ID No.2, wherein Xaa at position 4 is:
 - h) Pro
 - i) Gly
 - j) Val
 - k) Ile
 - l) Thr
4. An analogue of GRP having Seq. ID No.2, wherein Xaa at position 9 is:
 - m) Thr

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- n) Lys
5. An analogue of GRP having Seq. ID No.2, wherein Xaa at position 14 is:
- o) Met
 - p) Leu
6. An analogue of GRP having Seq. ID No.2, wherein Xaa at position 19 is:
- q) Asn
 - r) Lys
7. An analogue of GRP having Seq. ID No.2, wherein Xaa at position 27 is:
- s) Met
 - t) Leu
8. An analogue of GRP having Seq. ID No.2, wherein the ϵ -amino group of one or more Lys attached/linked with a lipophilic substituent via:
- u) a spacer
 - v) C-1-6-ester
 - w) an amide
 - x) C-1-6-alkylamide
 - y) C-1-6-dialkylamide
 - z) a Fmoc derivative
 - aa) a pharmaceutically acceptable salt
9. An analogue of GRP having Seq. ID No.2, wherein the spacer is:
- ab) an unbranched alkane α , ω -dicarboxylic acid group having from 1 to 7 methylene groups

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- ac) an unbranched alkane α , ω -dicarboxylic acid group having two methylene groups
 - ad) an amino acid except Cys
 - ae) a dipeptide
10. An analogue of GRP having Seq. ID No.2, wherein the acyl group is:
- af) selected from the group $\text{CH}_3(\text{CH}_2)_n\text{CO}-$, wherein n is 4-38
 - ag) $\text{CH}_3(\text{CH}_2)_6\text{CO}-$
 - ah) $\text{CH}_3(\text{CH}_2)_8\text{CO}-$
 - ai) $\text{CH}_3(\text{CH}_2)_{10}\text{CO}-$
 - aj) $\text{CH}_3(\text{CH}_2)_{12}\text{CO}-$
 - ak) $\text{CH}_3(\text{CH}_2)_{14}\text{CO}-$
 - al) $\text{CH}_3(\text{CH}_2)_{16}\text{CO}-$
 - am) $\text{CH}_3(\text{CH}_2)_{18}\text{CO}-$
 - an) $\text{CH}_3(\text{CH}_2)_{20}\text{CO}-$
 - ao) $\text{CH}_3(\text{CH}_2)_{22}\text{CO}-$
 - ap) selected from the group comprising $\text{HOOC}(\text{CH}_2)_m\text{CO}-$, where m is from 4-38
 - aq) selected from the group comprising $\text{HOOC}(\text{CH}_2)_m\text{CO}-$, where m is from 4-24
 - ar) $\text{HOOC}(\text{CH}_2)_{14}\text{CO}-$
 - as) $\text{HOOC}(\text{CH}_2)_{16}\text{CO}-$
 - at $\text{HOOC}(\text{CH}_2)_{18}\text{CO}-$

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au) $\text{HOOC}(\text{CH}_2)_{20}\text{CO}-$ av) $\text{HOOC}(\text{CH}_2)_{22}\text{CO}-$

11. The derivative of GRP, wherein the lipophilic substituent comprises:

aw) a group of formula $\text{CH}_3(\text{CH}_2)_p((\text{CH}_2)_q\text{COOH})\text{CHNH-CO}(\text{CH}_2)\text{CO}-$,wherein $p + q$ is an integer of from 8 to 33ax) a group of formula $\text{CH}_3(\text{CH}_2)_p((\text{CH}_2)_q\text{COOH})\text{CHNH-CO}(\text{CH}_2)\text{CO}-$,wherein $p + q$ is an integer of from 12 to 28ay) a group of formula $\text{CH}_3(\text{CH}_2)_r\text{CO-NHCH}(\text{COOH})(\text{CH}_2)_2\text{CO}-$, wherein r is an integer of from 10 to 24az) a group of formula $\text{CH}_3(\text{CH}_2)_r\text{CO-NHCH}(\text{COOH})(\text{CH}_2)_2\text{CO}-$, wherein r is an integer of from 8 to 24ba) a group of formula $-\text{NHCH}(\text{COOH})(\text{CH}_2)_4\text{NHCO}(\text{CH}_2)_u\text{CH}_3$, wherein r is an integer of from 8 to 18bb) a group of formula $-\text{NHCH}(\text{COOH})(\text{CH}_2)_4\text{NHCOCH}(((\text{CH}_2)_2\text{COOH})\text{NH-CO}(\text{CH}_2)_w\text{CH}_3$, wherein w is an integer of from 10 to 16bc) a group of formula $-\text{NHCH}(\text{COOH})(\text{CH}_2)_4\text{NHCO}(\text{CH}_2)_2\text{CH}(\text{COOH})\text{NH-CO}(\text{CH}_2)_x\text{CH}_3$, wherein x is an integer of from 10 to 16bd) a group of formula $-\text{NHCH}(\text{COOH})(\text{CH}_2)_4\text{NHCO}(\text{CH}_2)_2\text{CH}(\text{COOH})\text{NH-CO}(\text{CH}_2)_y\text{CH}_3$, where y is zero or an integer of from 1 to 22

be) 4-40 carbons

bf) 8-25 carbons

bg) hydrogenated cyclopentanophenanthrene

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bh) straight chain/branched alkyl group

bi) straight chain/branched fatty acid

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is an example of a generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

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inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant must choose one species from the Xaa groups, the lipophilic substituent group, the linking group between the lipophilic and ϵ -amino group of Lys, the spacer group, and the acyl group to be considered fully responsive.

Upon the species selection from the Xaa groups, Applicant is requested to submit a paper and CRF reflecting the combined amino acid elections.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on Monday through Friday, 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ELIZABETH KEMMERER
PRIMARY EXAMINER

GC
Art Unit 1646
7 June 2004